UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Z.H. by and through KEVIN HUTCHENS and CHRISTIN HUTCHENS, individually, and as parents and next friends of Z.H.	)	**CASE NO.1:14CV176**
Plaintiffs,	)	**JUDGE CHRISTOPHER A. BOYKO**
Vs.	)	
ABBOTT LABORATORIES, INC. and ABBVIE, INC.	)	**OPINION AND ORDER**
Defendant.	)	

CHRISTOPHER A. BOYKO, J:

This matter is before the Court on the Motion for Summary Judgment by Defendants Abbott Laboratories, Inc. and Abbvie, Inc. (ECF # 57). For the following reasons, the Count grants, in part and denies, in part, Defendants' Motion.

Plaintiffs Kevin and Christin Hutchens, parents of Plaintiff Z.H., a minor, are Ohio residents. Defendant Abbott Laboratories is an Illinois corporation. Defendant AbbVie, Inc. is a Delaware corporation with its principal place of business in Illinois.

According to the First Amended Complaint, Z.H. was born in 2003 with a number of

severe birth defects allegedly caused by Christin's use of Depakote, an anti-seizure medication formulated, tested, manufactured and marketed by Defendants during her pregnancy. Depakote has been approved and sold in the United States since 1978 for the treatment of certain forms of epilepsy. Depakote is promoted as an effective anti-epileptic drug ("AED"). However, Plaintiffs allege Depakote is defective and dangerous for its intended use because the primary compound in Depakote, valproic acid, is teratogenic (of, relating to, or causing developmental malformations) - i.e.- causes severe birth defects if taken during the first trimester of pregnancy. Among the birth defects known to be caused by first trimester exposure to Depakote are spina bifida, cleft palate, limb and digital deformities, facial dysmorphism, mental development delays, genitourinary malformations and heart defects. According to Plaintiffs, Depakote is riskier than other AEDs for women who are or may become pregnant and Defendants were aware of the heightened risks of birth defects from Depakote, yet they continue to market and distribute it in the United States without adequate warnings.

According to Plaintiffs, Defendants failed to communicate the heightened risk of birth defects to doctors and women but instead sought to minimize the risks and downplay the dangers in their product labeling. Defendants further marketed Depakote for off-label uses despite the knowledge of the risks. This is particularly troubling since the damage to the developing child is done often before a woman even knows she is pregnant.

Due to Defendants' alleged breaches of their duty of reasonable care, breaches of their express and implied warranties and their misrepresentations and omissions concerning the known risks of Depakote, Plaintiffs allege they have been injured. Z.H. was born with

heart defects, hypospadias, limb defects and developmental delay, as well as other congenital malformations and birth defects. Plaintiffs allege Ohio state law claims, including Strict Products Liability for Design Defect under O.R.C. 2307.75, Strict Products Liability for Inadequate Warning under O.R.C. 2307.76, Strict Products Liability for Nonconformance with Representations under O.R.C. 2307.77, Negligence, Gross Negligence, Negligent Misrepresentation and Fraud, Breach of Implied Warranty, Breach of Express Warranty, Intentional Infliction of Emotional Distress, Negligent Infliction of Emotional Distress and Loss of Consortium.

Defendants have moved for summary judgment on all Plaintiffs' claims. Defendants contend Depakote packaging contained a Black Box warning on the Depakote label at the time Christin got pregnant in 2002. This Black Box warning was the strongest warning permitted under FDA regulations. Defendants further contend they provided physicians with sufficient warnings that reasonably disclosed the risks of birth defects. Relying on the Sixth Circuit decision in *Ackley v. Wyeth Laboratories, Inc*., 919 F.2d 397 (6th Cir. 1990), Defendants argue that Ohio law does not require that a warning label provide a comparison of the dangers of Defendants' drug compared with other AEDs. Furthermore, even if Ohio law imposed such a duty on Defendants, Christin's physician would still have prescribed Depakote to Christin because the physician knew of the greater risks of Depakote from her study of relevant medical literature, yet still determined it was the best option for treating Christin's seizures.

Defendants challenge Plaintiffs' claims that Depakote caused Z.H.'s cognitive developmental delay because Plaintiffs lack competent medical evidence supporting such a

causal relationship. Also, the FDA would not have permitted such a warning on the Depakote label because there was no clear scientific evidence supporting this conclusion back in 2002. This is supported by Defendants' attempts to have just such a warning added to its label in 2005 and 2007 and both times the FDA rejected Defendants' attempts to include the cognitive development warning. Thus, according to Defendants, federal law preempts Plaintiffs' state law claims arising from any alleged failure to warn of any cognitive development delay.

Defendants move for summary judgment on Plaintiffs' design defect claim, which alleges the Depakote warning label was defective. Defendants argue that the Depakote label adequately warned about the risks. Plaintiffs offer no evidence that the drug Depakote itself was defectively designed, in fact, Christin still takes Depakote because it has provided the best relief of her seizure symptoms with the fewest side effects. Furthermore, for Plaintiffs to prevail on a claim that Depakote is defective they must demonstrate by expert testimony that the risks of Depakote outweigh the benefits. Plaintiffs have offered no such testimony. Also, Plaintiffs cannot show a better alternative existed in 2002. Lastly, when the FDA approves a drug, federal regulations prohibit changes to formulation.

Defendants further challenge Plaintiffs' breach of warranty claims, contending that the "learned intermediary doctrine" insulates Defendants from liability. Even if the doctrine does not apply, Plaintiffs did not rely on any representation by Defendants but instead relied on the representations of Christin's physician. Defendants argue that all Plaintiffs' common law claims are abrogated by the Ohio Product Liability Act ("OPLA") and move for summary judgment on Plaintiffs' demand for punitive damages because the FDA has not found Defendants committed fraud and Plaintiffs cannot show conscious disregard for the rights and

safety of Depakote users.

LAW AND ANALYSIS

Standard of Review

Summary judgment shall be granted only if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *See* Fed.R.Civ.P. 56(a). The burden is on the moving party to conclusively show no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Lansing Dairy. Inc. v. Espy*, 39 F.3d 1339, 1347 (6th Cir. 1994). The moving party must either point to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, admissions, interrogatory answers, or other materials" or show "that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." *See* Fed.R.Civ.P. 56(c)(1)(A), (B). A court considering a motion for summary judgment must view the facts and all inferences in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Once the movant presents evidence to meet its burden, the nonmoving party may not rest on its pleadings, but must come forward with some significant probative evidence to support its claim. *Celotex*, 477 U.S. at 324; *Lansing Dairy*, 39 F.3d at 1347.

This Court does not have the responsibility to search the record *sua sponte* for genuine issues of material fact. *Betkerur v. Aultman Hospital Ass 'n.*, 78 F.3d 1079, 1087 (6th Cir. 1996); *Guarino v. Brookfield Township Trustees*, 980 F.2d 399, 404-06 (6th Cir. 1992). The

burden falls upon the nonmoving party to "designate specific facts or evidence in dispute," *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 249-50 (1986); and if the nonmoving party fails to make the necessary showing on an element upon which it has the burden of proof, the moving party is entitled to summary judgment. *Celotex*, 477 U.S. at 323. Whether summary judgment is appropriate depends upon "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Amway Distributors Benefits Ass 'n v. Northfield Ins. Co.*, 323 F.3d 386, 390 (6th Cir. 2003) (quoting *Anderson*, 477 U.S. at 251-52).

Count I Strict Products Liability Design Defect O.R.C. 2307.75, **Negligent Design and Breach of an Implied Warranty**

Plaintiffs' First Amended Complaint alleges Depakote was defective in its design or formulation "because it when it left the hands of Defendants, the forseeable risks of the product exceeded the benefits associated with its design or formulation;" (FAC pg 9 at 34) and "it was more dangerous than an ordinary consumer would expect" (Id at 35) and there were alternative AEDs available with less teratogenic risks but comparable efficacy. O.R.C. 2307.75, in effect during the relevant time period, stated in pertinent part:

> a product is defective in design or formulation if either of the following applies:(1) When it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section;(2) It is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

As stated above, O.R.C. 2307.75 offers two alternative methods for determining whether a product is defective: 1) "a risk-benefit test in subsection (A)(1), and a consumer-

expectations test in subsection (A)(2)." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 529 (6th Cir. 2012) citing *Perkins v. Wilkinson Sword, Inc*., 83 Ohio St.3d 507, 700 N.E.2d 1247, 1248 (1998). "Under the risk-benefit theory, a court weighs the existing design's foreseeable risks against its benefits, as determined by a nonexclusive statutory list of factors." *Newell*, 676 F.3d at 529. "Under the consumer-expectations theory, a product may be defectively designed if "[i]t is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." *Id.* at 530. "Ohio law generally does not require expert testimony under the consumer-expectations theory." *Id.* Although Plaintiffs need not retain an expert to opine on a defective formulation claim under the consumer-expectation theory, "a plaintiff cannot simply sit back and highlight deficiencies in the defendant's argument without providing some affirmative support for its own position." *Id* at 533.

Defendants argue they are entitled to summary judgment on Plaintiffs' claim for defective design and formulation because Plaintiffs fail to identify a defect in the design or formulation of Depakote; in fact, Christin still takes Depakote because it controls her symptoms. Defendants also contend they are entitled to summary judgment because Plaintiffs offer no expert testimony that Depakote's risks outweigh its benefits as required under Ohio law. Because Depakote is a Category D drug, the FDA has already determined its efficacy outweighs its risks and Plaintiffs offer no evidence of a viable alternative formulation for Depakote in 2002.[1] Lastly, Defendants argue that once the FDA approves a formulation, a

[1] Category D is a pregnancy category assigned to certain drugs based on the FDA's assessment of the risk of fetal injury as relates to the use of the drug. A Category D assignment means there is positive evidence of fetal risk but the benefits may warrant use in spite of such risks.

manufacturer is prohibited from altering it, therefore, Plaintiffs' claim for defective formulation is preempted by the federal law.

Plaintiffs' Brief in Opposition to Defendants' Motion for Summary Judgment offers no argument or evidence rebutting Defendants' challenges to Plaintiffs' defective design claim. Therefore, Plaintiffs have waived their defense and Defendants are entitled to summary judgment on Count One of Plaintiffs' Complaint for Design Defect under O.R.C. 2307.75. "[P]laintiff has not raised arguments in the district court by virtue of his failure to oppose defendants' motions to dismiss, the arguments have been waived." *Humphrey v. U.S. Attorney Gen.'s Office*, 279 F. App'x 328, 331 (6th Cir. 2008). See also *Scott v. State of Tennessee*, 878 F.2d 382, 1989 WL 72470, at *2 (6th Cir.1989) (unpublished table decision) (noting "if a plaintiff fails to respond or to otherwise oppose a defendant's motion, then the district court may deem the plaintiff to have waived opposition to the motion."). Because elements of strict liability are identical to those for breach of implied warranty, failure to prove a defect is fatal to both claims. See *In Re Whirlpool*, 722 F.3d 838, 853 (6th Cir. 2013). For these same reasons, Plaintiffs' negligent design claim fails as well. See *Tipton v. Michelin Tire, Co.* 101 F.3d 1145, 1150 (6th Cir. 1996).

Even if Plaintiffs had offered a response, Defendants would still be entitled to summary judgment on Plaintiffs' defective design claim because Plaintiffs offered no expert testimony that Depakote's formulation's risks outweigh its benefits. See *Newell Rubbermaid, Inc. v. Raymond Corp.,* 676 F.3d 521, 529 (6th Cir. 2012) "Ohio law requires expert testimony where aspects of the defect or the proposed alternative designs are technically complex and outside the understanding of a lay juror." Therefore, Defendants are entitled to

summary judgment under a risk-benefit theory.

As the Sixth Circuit stated in *Newell*, although expert testimony is not typically required under a consumer-expectations theory, Plaintiff must still proffer some affirmative support for its claim. Because Plaintiff fails to point the Court to any evidence of consumer expectation, Plaintiffs' claim fails on this theory as well.

Even if Plaintiffs had attempted to meet their burden under either the risk-benefit or consumer-expectations theories they must also show there was no "practical and technical feasible alternative design that...that would have prevented the harm for which the claimant seeks to recover..." O.R.C. 2307.75(F); *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp.3d 1115, 1124 (S.D. Ohio 2014) ("Although this subsection does not state that it is a plaintiff's burden to prove an alternative design, the Sixth Circuit has so held." (citing *McGrath v. Gen. Motors Corp.*, 26 Fed.Appx. 506, 510 (6th Cir.2002)).

Plaintiffs offer no expert testimony on a viable alternative. In fact, Christin remains on Depakote to this day because it works best at controlling her seizures of the seven different seizure meds she has tried. (Hutchens depo 72-73). Hutchens testified Depakote, in combination with Lamictal, is the only one that controlled her seizures. (Id.). Lamictal by itself did not control her seizures as well. (Id. at 77).

In light of Hutchens' testimony and the absence of expert testimony that a feasible alternative design would have prevented the harm, Defendants are entitled to summary judgment on Plaintiffs' defective design, negligent design and breach of implied warranty claims.

Count II Strict Liability Due to Inadequate Warning O.R.C. 2307.76

Count II of Plaintiffs' First Amended Complaint alleges damages arising out of Defendants' failure to warn Plaintiffs that Depakote was unreasonably dangerous as confirmed by extensive published literature and Defendants' own data. In spite of this knowledge, Defendants never adequately warned of the increased teratogenic risks associated with Depakote use. Defendants allegedly also knew that higher doses of Depakote and combining Depakote with other AED's substantially increased the risk of teratogenic effects compared to lower doses or monotherapy use, yet failed to provide adequate warnings.

According to Plaintiffs, Defendants further failed to warn of the significant increases of birth defects, including impaired cognitive function, neurodevelopmental delay, autism and autism spectrum disorders and additional risk to women in childbearing years. Defendants lacked adequate post-market or post-approval warnings to consumers and/or health care providers on the risks of fetal death and major congenital malformations compared to other AEDs.

In 2002, Depakote contained a Black Box warning label that read:

> VALPROATE CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA). ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS. (Ex. 3, 2002 Physicians' Desk Reference ("PDR") at 430).

Depakote further contained a "Warnings" section consisting of a number of paragraphs concerning potential birth defects and included the following warning:

> OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND

INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED."

The 2002 Depakote label also contained a warning on fetal risks:

"**POSITIVE EVIDENCE OF RISK.** Studies in humans, or investigational or post-marketing data, have demonstrated fetal risk. Nevertheless, potential benefits from the use of the drug may outweigh the potential risk. For example, the drug may be acceptable if needed in a life threatening situation or serious diseases for which safer drugs cannot be used or are ineffective."
(Ex. 6, 2002 FDA Key to Use-in-Pregnancy at 342) (emphasis in original)).

Based on the above warnings, Defendants believe the labels satisfied the requirements of Ohio law in providing adequate warnings of the risks associated with Depakote use.

O.R.C. 2307.76 reads in pertinent part:

(A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:

(1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

(b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

(2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

(a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;

> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (B) A product is not defective due to lack of warning or instruction or inadequate warning or instruction as a result of the failure of its manufacturer to warn or instruct about an open and obvious risk or a risk that is a matter of common knowledge.

Plaintiffs also allege negligent failure to warn under Ohio law. The Court will address both the strict liability and negligent failure to warn claims together.

"Under Ohio statutory law, a manufacturer is subject to liability for compensatory damages based on a product liability claim if the Plaintiffs prove, by a preponderance of the evidence, that the label was defective due to inadequate warning or instruction and the defect was the proximate cause of [Defendant's] injury." *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 760 (S.D. Ohio). "A claim for negligent failure to warn has three basic elements: (1) a duty to warn against reasonably foreseeable risks; (3) breach of such a duty; and (3) injury that is proximately caused by the breach." *Reece v. Astrazeneca Pharm., LP*, 500 F.Supp.2d 736, 751 (2007). "The manufacturer must give suitable warning of a dangerous propensity that may result from use of the product." *Id.* "Because the standard for failure to warn requires that a manufacturer exercise reasonable care, the same standard applies for both strict liability and negligence claims for inadequate warning." *McConnell v. Cosco, Inc.*, 238 F.Supp.2d 970, 976 (2003) (citing *Crislip v. TCH Liquidating Co.*, 52 Ohio St.3d 251, 566 N.E.2d 1177, 1183 (1990)). Generally, whether a warning is sufficient in light of the known risks is a question of fact for the trier of fact. "However, 'where the warning is accurate, clear, and unambiguous,' it is a question of law." *In re Meridia Prod. Liab. Litig.*,

328 F. Supp. 2d 791, 812 (N.D. Ohio 2004). "To be considered adequate, a warning concerning a prescription drug generally must contain a full and complete disclosure of the potential adverse reactions to the drug." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn.1994). "Put differently, 'a warning is 'adequate' ... where, under all the circumstances, it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist.'" *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. at 812 quoting *Seley v. G.D. Searle & Co.*, 67 Ohio St.2d, 192, 198, (1981).

The Court finds genuine issues of fact preclude summary judgment for Defendants on Plaintiffs' inadequate warning claims. Courts that have considered the issue agree that black box warnings on drug labels are the strongest warnings available under the FDA regulations. See *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 386 (6th Cir. 2013)(black box warnings are "the strongest available under FDA regulations.") See also *Howland v. Purdue Pharma L.P.*, 104 Ohio St. 3d 584, 584, (2004), (black box warning is "the strongest warning for an FDA-approved drug."). However, this Court is unaware of any court holding that such a warning is per se adequate as a matter of law. Rather, courts must consider the adequacy of the warning in light of the known risks.

Neither is the warning label per se adequate if the label indicates that the FDA assigned a Category D designation to the drug. The courts that have considered this have rejected the idea that such a designation is sufficient on its own because the label still points the reader to additional warnings contained elsewhere with the drug. See *Rheinfrank,* 119 F.Supp.2d at 771, *In re Depakote*, No.14CV847 2015 WL 4776093, at *5 (S.D. Ill. Feb. 14, 2015). "Additionally, federal regulations do not limit drug manufacturers from strengthening

their warnings to reflect new developments and comply with state laws." *Id.* citing *Wyeth v. Levine*, 555 U.S. 555, 568–569 (2009) (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)). The Supreme Court has explained that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id*. at 570–571. Thus, the Court agrees with the Illinois and Ohio court decisions finding the Black Box label and Category D designation do not render the label adequate as a matter of law when opposed by competent evidence creating an issue of fact that the label warning is inadequate.

Plaintiffs point to several alleged inadequacies on the Depakote label. First, Plaintiffs' contend the medical literature up to 2003 showed increased risks of teratogenicity from Depakote usage than other AEDs; demonstrated a causal link between congenital defects and Depakote, suggested Depakote not be given during pregnancy and suggested that physicians reduce daily dosages and use monotherapy for women of childbearing age. Comparing these findings to the actual warnings on the Depakote label, Plaintiffs' expert Dr. Cheryl D. Blume, Ph.D. in Pharmacology and Toxicology, opines that the Depakote label was inadequate and misleading when it read "reports indicate a possible similar association with the use of other [AEDs]." (Blume Report ¶ 161). In fact, the literature at the time, according to Blume, indicated a higher incidence of birth defects. Plaintiffs further contend that medical literature indicated a cause and effect relationship between Depakote use and congenital anomalies (See Report of Lemuel A. Moye, M.D., Ph.D ¶158-160), yet the Depakote label reads "the higher incidence of congenital anomalies in antiepileptic drug-

treated women with seizure disorders cannot be regarded as a cause and effect relationship." Dr Moye opines that adequate methodologies existed prior to 2002 to determine drug teratogenicity in humans but the Depakote label stated "there are intrinsic methodologic problems in obtaining adequate data on drug teratogenicity in humans." Dr. Moye also opines Depakote's label makes a false representation that there was a 1-2% risk of neural tube defects arising from Depakote use when the available medical literature placed the risk as high as 5.4%. These are just some of Defendants' alleged misrepresentations and omissions Plaintiffs contend a jury could find inadequately warned of the risks associated with Depakote use.

These expert opinions concerning what was known of the relationship between Depakote and birth defects in the available medical literature and what Defendants knew or should have known about the risks as compared to what was conveyed on the Depakote drug label clearly establish issues of fact for a jury to consider when determining the adequacy of the Depakote label.

Comparative Risks and Learned Intermediary

Defendants contend they had no obligation to warn of comparative risks between the use of Depakote versus other AEDs on the Depakote label under established Ohio law. In *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990), the Sixth Circuit held "the manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug. *(Internal citation omitted).* It is not obligated to provide a comparison of its drug with others."

Plaintiffs agree that Ohio law imposes no such duty, however, because the Depakote

label affirmatively represented its risks as similar to those of other AEDs when such a comparison is arguably false, this false representation may render the label inadequate. The *Rheinfrank* court agreed with Plaintiffs that by making such an affirmative comparison Defendants created an issue of fact whether its Depakote label was adequate in light of evidence at the time that Depakote's teratogencity was greater than other AEDs. This Court agrees and finds it an issue of fact for the jury on the adequacy of Defendants' labeling.

Under the "learned intermediary doctrine" a " manufacturer satisfies his duty to warn of dangers associated with use of the product by providing adequate warnings to the medical profession, and not the ultimate user." *Seley*, 67 Ohio St. 2d at 202–03. Here, Defendants contend Dr. Nancy Foldvary, a neurologist specializing in the treatment of epilepsy and Christin's treating neurologist, was provided adequate warnings on the use of Depakote and its potential teratogenicity. Dr. Foldvary published a chapter in a book on the treatment of epilepsy which contained a section on birth defect risks from AED use, including Depakote. Both Hutchens and Dr. Foldvary testified that the doctor warned Hutchens about the risk of serious birth defects from the use of Depakote during pregnancy. (C. Hutchens depo pg. 137). However, Hutchens said she was told the risk was in developing spina bifida or cleft palate and the incidence was low 1-2%. (Id.). Dr. Foldvary also testified that based on her knowledge on teratongenic effects of Depakote as compared to other AEDs in 2002, she would have told Plaintiffs that Depakote was starting to "stand out." (Foldvary depo pg. 175).

Defendants cite to Dr. Foldvary's knowledge and expertise concerning AEDs and birth defects in support of their argument that even if the Depakote label were inadequate, it

would have made no difference in Dr. Foldvary's decision to prescribe Depakote for Hutchens. Under Ohio law, "where, as here, an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug... the required element of proximate cause between the warning and ingestion of the drug is lacking." *Seley*, at 201. According to Defendants, Dr. Foldvary relied on her own knowledge of the literature on AEDs and birth defects when she prescribed Depakote to Hutchens, even though she knew it was emerging in the literature as more dangerous than other AEDs. Furthermore, in her book chapter, Dr. Foldvary cited two published articles that allegedly reported that Depakote had a higher risk of birth defects than other AEDs. Because Dr. Foldvary was aware of the relevant literature at the time she prescribed Depakote to Hutchens, Defendants contend any inadequacy of the warning label was not the proximate cause of Z.H.'s injuries.

Plaintiffs point to Dr. Foldvary's deposition testimony in opposition to Defendants' argument on causation. When questioned whether she would have informed Plaintiffs of the higher risks of birth defects arising from Depakote, had she known it in 2002, Dr. Foldvary testified she would have but she was unaware of the higher risks. (Foldvary depo. Pg. 169). Plaintiff's treating Nurse Practitioner, Sharon Ginal, testified had she known of the heightened risks of birth defects from Depakote use she would have counseled against Depakote use and prescribed something else. (Ginal depo. Pg. 84). Dr. Foldvary also testified:

> Q. Okay. Specifically at that time, if you had known that Depakote carried a significantly higher risk of causing birth defects than the other AEDs, would you have informed Christin and Kevin of that fact?
>
> A. Yep.

> Q. On June 19, 2002, were you aware that Depakote carried a significant higher risk of causing birth defects than the other AEDs?
>
> A. No. What I was aware of was that there was an – there was a possibility of an increased risk. When you use the word "significant," that is a word that I have trouble with because none of the literature at that time was quite designed well enough to test for significance.

Furthermore, Hutchens testified that if she knew of the greater risks she would not have taken Depakote.

Because Dr. Foldvary's knowledge on the literature at the time is an issue of fact, and because she testified she could not tell whether the higher risk of birth defects was significant when she prescribed Depakote to Hutchens, it is a question of fact for the jury to determine whether the Dr. Foldvary would have prescribed Depakote to Hutchens if Depakote's warning label was adequate.

Cognitive Delay and Federal Preemption

According to Defendants, Plaintiffs cannot recover for Z.H.'s cognitive delay because it is caused by Z.H.'s microcephaly which he acquired post-natally and Plaintiffs offer no evidence that Depakote causes post-natal microcephaly. Furthermore, federal law preempts Plaintiffs' claim for developmental delay because the evidence demonstrates the FDA would not have permitted Defendants to include on the Depakote label a warning about developmental delay prior to 2009. The courts in both *Rheinfrank* and *In re Depakote* ruled in favor of Defendants on this very issue. Finding that attempts by Depakote in 20006 and 2008 to amend its warning label to include warnings of developmental delay due to Depakote use were rejected by the FDA, the courts found Plaintiffs' claims for inadequate warnings of developmental delay were preempted by federal law. Plaintiffs now agree they will not argue

that Defendants failure to warn of the risks of developmental delay on its 2002 Depakote label rendered the warning in adequate, but instead argue they may still offer evidence of damages arising from Z.H.'s cognitive delay.

The Court will not rehash the arguments for and against preemption as Plaintiffs have agreed they will not raise it for purposes of establishing that the 2002 Depakote warning label was inadequate. The Court will reserve any determination on the damages evidence to be presented at trial on Z.H.'s cognitive delay for its rulings on the pending motions in limine which address this subject.

Therefore, the Court finds Plaintiffs' claim that Defendants' failure to warn of the risks of cognitive developmental delay from use of Depakote by women of childbearing age renders its label inadequate is preempted by federal law.

Nonconformance with Representations and Breach of Express Warranty

Plaintiffs allege Depakote failed to conform to the representations made in its product label that the benefits of Depakote use in treating seizure disorders outweighed its risks. Under Ohio law, the OPLA claim for failure to conform under O.R.C. § 2307.77 is a codification of breach of express warranty. *Saraney v. TAP Pharm. Prod., Inc.*, No. 104 CV 02026, 2007 WL 148845, at *7 (N.D. Ohio Jan. 16, 2007).

Under O.R.C. § 2307.77, a product is defective if it:

> did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

"Representation" is defined as an "express representation of a material fact concerning the character, quality, or safety of a product." *Saraney*, at *8, quoting O.R.C. § 2307.71(O).

To prevail on a claim for failure to conform, Plaintiffs must offer evidence that: (1) the manufacturer made representation as to a material fact concerning the character or quality of the product; (2) the product did not conform to that representation; (3) plaintiffs justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiffs' injuries. *Id.*

Defendants move for summary judgment on Plaintiffs' failure to conform and breach of express warranty claims because the learned intermediary doctrine encompasses such claims and because Christin admits she never read the label and never received any representations from Abbott.

Plaintiffs Brief in Opposition contains no argument or evidence opposing the failure to conform and breach of warranty claims specifically and Defendants, in their Reply, argue Plaintiffs have abandoned these claims.

The Court disagrees. Plaintiffs' Brief in Opposition discusses why the learned intermediary doctrine does not shield Defendants from liability "if the warnings they provided to physicians would not permit the physicians to adequately advise their patients." *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d at 811. The Court has already found questions of fact prohibit summary judgment for Defendants on the adequacy of the warnings given to Dr. Foldvary and Nurse Ginal. Second, reliance is an issue of fact, considering the disputed adequacy of the warnings given to Plaintiffs' medical professionals. Because failure to conform arises from the safety of a product, this claim survives.

Abrogation

The OPLA defines a product liability claim as "a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:

> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> (c) Any failure of that product to conform to any relevant representation or warranty.
> Ohio Rev. Code Ann. § 2307.71 (West).

Defendants argue that all Plaintiffs' Ohio common law claims are abrogated by the OPLA, as each seeks damages for personal injuries caused by Defendants' failure to warn of the risks associated with use of Depakote.

O.R.C. 2307.71(B) states:

"(B) Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." The abrogation clause was added in 2005, two years after Z.H. suffered injury allegedly due to Defendants' inadequate warnings on the Depakote label. According to Defendants, Plaintiffs claims did not accrue until after 2005 because Plaintiffs did not learn of Defendants alleged wrongdoing until the commencement of the action in 2014. Therefore, Defendants are entitled to summary judgment on Defendants negligence, gross negligence, negligent misrepresentation and fraud, breach of implied and express warranties, intentional and negligent infliction of emotional distress claims.

Plaintiffs cite to *Kiker v. Smithkline Beecham Corp.*, No 2:14CV2164, 2015 WL

5768389 (S.D. Ohio Sept 30, 2015) for the proposition that courts look to when a claim "arises" -i.e. when the injurious act occurred, as opposed to when the cause of action "accrued" -i.e- when the injured party becomes aware or should have become aware of the injury. See *In. Re: E.I Du Pont de Nemuers & Co.,* No. 2-13md2433 Dkt No. 4215 at *9 (S.D. Ohio Sept 8 2015). Because the injury occurred in 2002 before the abrogation clause was added, Plaintiff argues its claims are not abrogated by the OPLA.

Under Ohio law, "prior to 2005, three common law theories of recovery existed in Ohio product liability litigation: (1) breach of contract based on either express or implied warranty; (2) strict liability/implied warranty in tort; and (3) negligence." *Quill v. Albert M. Higley Co.,* 2014 Ohio 5821, ¶ 35, 26 N.E.3d 1187, 1194–95, citing *Temple v. Wean United, Inc.,* 50 Ohio St.2d 317, 320, 364 N.E.2d 267 (1977). In 1997, the Ohio Supreme Court in *Carrel v. Allied Products Corp.,* 78 Ohio St.3d 284, 677 N.E.2d 795 (1997), held that the version of the OPLA in effect at that time lacked sufficiently strong language abrogating common law causes of action arising from product liability injuries.

In response to *Carrel,* the Ohio General Assembly, in 2005, amended the OPLA to include Section 2307.71(B), which states as follows: "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." The General Assembly stated that the 2005 amendment was: " Intended to supersede the holding of the Ohio Supreme Court in *Carrel v. Allied Products Corp.* that the common-law product liability cause of action of negligent design survives the enactment of the Ohio Product Liability Act, sections 2307.71 to 2307.80 of the Revised Code, and to abrogate all common law product liability causes of action." *Quill,* at 1194–95.

The abrogation amendment is not to be retroactively applied. See *Doty v. Fellhauer Elec., Inc.*, 175 Ohio App.3d 681 (6th Dist. Oh. 2008). Thus, the OPLA does not abrogate common law causes of action that accrued before April 7, 2005. *Id.*

The parties do not point the Court to any controlling authority on what version of the law should be applied to Plaintiffs' claims and there is a split, at least in the Southern District of Ohio, on this very issue. Defendants cite to three decisions from the Southern District of Ohio by three different judges, wherein the courts looked to the date the causes of action accrued, not when the injury occurred, to determine if the claims were abrogated. While the injuries occurred prior to the implementation of the OPLA abrogation clause, the causes of action accrued after. These courts reasoned that because the cause of action accrued when plaintiffs discovered the causal connection between the product and their injury, it is that date that determines the applicable law to be applied. *See Hempy v. Breg, Inc.*, 2012 WL 380119 (S.D. Ohio Feb. 6, 2012) (Frost, G.); *Deacon v. Apotex Corp.*, 2008 WL 2844652 (S.D. Ohio July 22, 2008) (Rice, J.); *Stratford v. SmithKline*, 2008 WL 2491965 (S.D. Ohio Jun. 17, 2008) (Graham, J.).

Plaintiffs argue that the date the injury occurred is the operative date and cite to *Kiker v. Smithkline Beecham Corp.*, No. 2:14CV2164, 2015 WL 5768389 (S.D. Ohio Sept. 9, 2015). In *Kiker*, the Court distinguished between the date a cause of action arises (when the conduct giving rise to cause of action occurred) and the date it accrues and held the date the action arises is the operative date.

However, the majority of courts that have considered this issue favor applying the accrual date.

The Court finds that its reading of Ohio law favors using the accrual date. In general, "absent legislative definition, it is left to the judiciary to determine when a cause "arose." *O'Stricker v. Jim Walter Corp.*, 4 Ohio St. 3d 84, 87, 447 N.E.2d 727, 730 (1983). On this issue however, the Ohio legislature has expressly described when an cause of action arises in a product liability claim for bodily injury. O.R.C. 2305.10 is captioned "Product Liability, bodily injury or injury to personal property: ***when certain causes of action arise***" (emphasis added). This section reads in pertinent part:

> (B)(1) For purposes of division (A) of this section, a cause of action for bodily injury that is not described in division (B)(2), (3), (4), or (5) of this section and that is caused by exposure to hazardous or toxic chemicals, ethical drugs, or ethical medical devices accrues upon the date on which the plaintiff is informed by competent medical authority that the plaintiff has an injury that is related to the exposure, or upon the date on which by the exercise of reasonable diligence the plaintiff should have known that the plaintiff has an injury that is related to the exposure, whichever date occurs first.

The Ohio Supreme Court's jurisprudence echoes the legislative language. "Generally, a cause of action accrues and the statute of limitations begins to run at the time the wrongful act was committed. (Internal citation omitted). However, the discovery rule is an exception to this general rule and ***provides that a cause of action does not arise*** until the plaintiff discovers, or by the exercise of reasonable diligence should have discovered, that he or she was injured by the wrongful conduct of the defendant." *Norgard v. Brush Wellman, Inc.*, 95 Ohio St. 3d 165, 167, 766 N.E.2d 977, 979 (2002).

Here, both the Ohio statute and Ohio Supreme Court precedent clearly hold that a cause of action does not arise and/or accrue until the plaintiff discovers the injury was caused by wrongful conduct. Because Plaintiff did not discover Z.H.'s injuries were allegedly

caused by Defendants' wrongful conduct until the filing of the Complaint, their causes of action did not arise or accrue until after the effective date of the abrogation clause. Therefore, all Plaintiffs' Ohio common law product liability claims are barred.

The OPLA includes "within its definition of "product liability claims" those based upon "[a]ny warning or instruction, or lack of warning or instruction, associated with th[e] product." *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 921 (N.D. Ohio 2009) Ohio Rev.Code § 2307.71(A)(13)(b). Therefore, the Court must determine whether each of Plaintiffs' common law claims constitute product liability claims abrogated by the OPLA.

Plaintiffs' common law claims include negligence, gross negligence, negligent misrepresentation and fraud, breach of implied and express warranties, intentional and negligent infliction of emotional distress. Courts considering the OPLA's preemption of common law causes of action have determined that the OPLA bars the following claims: *Nationwide Agribusiness Ins. Co. v. CNH America LLC*, 1:12-CV-01430, 2014 WL 2520502 (N.D. Ohio June 4, 2014)(common law claims of breach of warranty and strict liability are preempted by the OPLA); *Mitchell v. Proctor & Gamble*, 2:09-CV-426, 2010 WL 728222, 3 (S.D. Ohio Mar. 1, 2010)("The OPLA has been held to abrogate claims for strict products liability."); *McConnell v. Cosco, Inc.*, 238 F.Supp.2d 970, 974-76 (S.D. Ohio 2003)(Strict products liability claims in Ohio are governed by the OPLA). *See Saraney v. TAP Pharm. Prods.*, No. 1:04-CV-02026, 2007 U.S. Dist. LEXIS 3113, 2007 WL 148845 (S.D. Ohio January 16, 2007) (negligence claim is preempted by the OPLA); *Miller v. ALZA Corp.*, 759 F.Supp.2d 929, 943-44 (S.D. Ohio 2010)(common law claims of negligence, breach of express warranty and breach of implied warranty are abrogated by the OPLA); *Paugh v. R.J.*

Reynolds Tobacco Co., 834 F.Supp. 228, 230 (N.D. Ohio 1993) (allegations that there was negligence in how cigarettes were "tested, researched, sold, and promoted" fell under OPLA).

Here, Plaintiffs' negligence, gross negligence, breach of implied and express warranties and intentional and negligent infliction of emotional distress claims all arise out of Defendants' alleged failure to warn of Depakote's dangers. Thus, each one is a product liability claim barred by the OPLA.

Plaintiffs' allege an additional common law claim for Negligent Misrepresentation and Fraud. While any negligent misrepresentation is barred by the OPLA, fraud is not. See *Stratford*, 2008 WL 2491965, at *8 (" claims of active misrepresentation are not necessarily abrogated by the OPLA because they may implicate the more general duty not to deceive, rather than the duty to warn.") *Stratford* listed the following cases as holding a fraud claim was not abrogated by the OPLA:

> *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343 (6th Cir.2000) (fraud claims are based on the general duty not to deceive); *see Chamberlain*, 1999 U.S. Dist. LEXIS 2263, 1999 WL 33994451 (complaint for fraud that was grounded on allegations of breach of a general common law duty not to deceive rather than on allegations that the product did not conform to defendant's representations or warranties is not displaced by the OPLA); *Hollar v. Philip Morris Inc.*, 43 F.Supp.2d 794, 808 (N.D.Ohio 1998) (common law fraud claim is based primarily on defendant's breach of its alleged duty not to deceive and is not limited to a product liability claim).

Plaintiffs contend Defendants representations that Depakote was as safe or safer than other AEDs was false and Defendants knew it was false at the time it was made. Defendants further represented that Depakote's risk of terotogenicity was common to AEDs in general. This was also knowingly false according to Plaintiffs. Defendants' representation that there was no causal relationship between Depakote and birth defects was also knowingly false.

Given these representations Plaintiffs' claim for fraud is not abrogated by the OPLA because it alleges violation of Defendants' general duty not to deceive consumers and physicians. Therefore, summary judgment is denied on Plaintiffs' fraudulent representation claim.

Punitive damages

Defendants move for summary judgment on Plaintiffs' punitive damages claims, contending that punitive damages are barred under the OPLA if the FDA has not found fraudulent conduct by the manufacturer. See *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp. 3d 1115, 1130 (S.D. Ohio 2014) ("'claims that the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it' were also preempted.") quoting *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir.2012).

Plaintiffs do not oppose this argument and summary judgment is granted for Defendants on Plaintiffs' OPLA punitive damages claim.

However, Plaintiffs may pursue punitive damages under its state law fraud claim because the allegations and evidence create a genuine issue of fact whether Defendants alleged misrepresentations on the safety of Depakote evidenced a conscious disregard of the rights and safety of persons.

Therefore, for the foregoing reasons, the Court grants summary judgment for Defendants on Counts I, IV, V, VI (only as to the negligent misrepresentation) VII, VIII, IX and X. The Court denies Defendants' Motion on Counts II, III, VI (as to fraud) and XI. The Court grants Defendants Motion for Summary Judgment on Plaintiffs' punitive damages claim under the OPLA but denies it as to Plaintiffs' Ohio common law fraud claim. The Court further finds genuine issues of fact preclude summary judgment for Defendants on the

Learned Intermediary Doctrine.

IT IS SO ORDERED.

s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge

Dated: September 30, 2016